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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs, v. IVAX CORPORATION, IVAX PHARMACEUTICALS, INC., IVAX PHARMACEUTICALS NV, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC. and CIPLA, LTD. Defendants.	Consolidated Under 05-5533 (JAP) Original Civil Action No. 06-01057

AMENDED COMPLAINT

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under the Patent and Food and Drug laws of the United States, Titles 35 and 21, United States Code. Jurisdiction and venue are based on 28 U.S.C. §§ 1331, 1338(a), 1391(b), 1391(c), 1391(d), 1400(b), 2201, 2202 and 35 U.S.C. §§ 271(a), 271(b), 271(c), 271(e), 271(g), and/or 295.

2. On information and belief, IVAX Corporation, IVAX Pharmaceuticals, Inc., IVAX Pharmaceuticals NV, Inc., Teva Pharmaceuticals Industries Ltd., and Teva Pharmaceuticals USA, Inc. (jointly and severally "Teva") have been and are engaging in activities directed toward infringement of United States Patent Nos. 5,714,504 (the "'504 patent"); 5,877,192 (the "'192 patent"); 6,875,872 (the "'872 patent"); 6,369,085 (the "'085 patent"); and 5,948,789 (the "'789 patent"); by, inter alia, submitting an abbreviated new drug application designated ANDA No. 78-003 seeking FDA's approval to commercially manufacture, use and sell its proposed 20 mg and 40 mg product called "Esomeprazole Magnesium" (herein after referred to as "Esomeprazole Magnesium Capsules") containing the active ingredient esomeprazole magnesium.

3. On information and belief, Cipla, Ltd. ("Cipla") has and will continue to aid, abet, induce, contribute to, engage in activities directed towards and otherwise participate in the infringement of the '504, '192, '872, '085 and '789 patents by, inter alia, submitting a Drug Master File (DMF) seeking FDA approval to commercially manufacture, use and sell esomeprazole magnesium, supplying the bulk esomeprazole magnesium to be used in Teva's Esomeprazole Magnesium Capsules, importing and supplying the final Esomeprazole Magnesium Capsules to be marketed by Teva under ANDA No. 78-003, and otherwise aiding and abetting Teva in the preparation and submission of ANDA No. 78-003 and in its further

preparations to commercialize Teva's Esomeprazole Magnesium Capsules upon FDA approval of ANDA No. 78-003.

4. In Teva's notice letter entitled "Esomeprazole Magnesium 20 mg and 40 mg Capsules" (hereinafter referred to as the "Notice of Certification"), Teva has indicated that it intends to market its Esomeprazole Magnesium Capsules, which are to be manufactured and supplied by Cipla, before the expiration of the '504, '192, '872, '085 and '789 patents.

5. Teva's submission of ANDA No. 78-003 and Cipla's submission of the DMF, in addition to service of Teva's Notice of Certification, indicate a refusal to change ~~its~~ their current course of action.

6. There has been and is now an actual, justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, have and will continue to induce, contribute to, engage in activities directed toward or otherwise aid and abet said infringement of the '504, '192, '872, '085 and '789 patents.

THE PARTIES

7. Plaintiff AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at Södertälje, Sweden. AstraZeneca AB was a corporate name change from Astra Aktiebolaget.

8. Plaintiff Aktiebolaget Hässle ("Hässle") is a company organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

9. Plaintiff AstraZeneca LP is a limited partnership organized under the laws of Delaware, having its principal place of business at Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and

Drug Administration ("FDA") for an esomeprazole magnesium formulation which it sells under the name NEXIUM®.

10. Plaintiff KBI Inc. ("KBI") is a Delaware corporation having it principal place of business at Whitehouse Station, New Jersey.

11. Plaintiff KBI-E Inc. ("KBI-E") is a Delaware corporation, having its principal place of business at Wilmington, Delaware. KBI and KBI-E have exclusive rights in the United States to the patents-in-suit.

12. On information and belief, defendant Ivax Corporation is a Florida corporation, having a principal place of business at 4400 Biscayne Blvd., Miami, Florida and having a place of business at 140 Legrand, Northvale, New Jersey. On information and belief, defendant Ivax Corporation is a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.

13. On information and belief, defendant Ivax Pharmaceuticals, Inc. is a wholly owned subsidiary of Ivax Corporation, having a place of business at 4400 Biscayne Blvd., Miami, Florida and 140 Legrand, Northvale, New Jersey.

14. On information and belief, defendant Ivax Pharmaceuticals NV, Inc. is a wholly owned subsidiary of Ivax Pharmaceuticals, Inc., which in turn is a wholly owned subsidiary of Ivax Corporation, having a place of business at 140 Legrand, Northvale, New Jersey.

15. On information and belief, defendant Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation, Ivax Pharmaceuticals, Inc. and Ivax Pharmaceuticals NV, Inc. on January 26, 2005.

16. On information and belief, defendant Teva Pharmaceutical Industries Ltd. is an Israeli Corporation, having a principal place of business at 5 Basel St., P.O. Box 3190, Petach Tikva 49131, Israel.

17. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a Delaware Corporation, a wholly owned subsidiary of Orvet UK, which is a wholly owned subsidiary of Teva Pharmaceuticals Europe, which is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., having a principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454, and having a place of business at 8 Gloria Lane, Fairfield, New Jersey 07004.

18. On information and belief, defendant Cipla, Ltd. is an Indian entity having a place of business at Mumbai Central, Mumbai 400 008, India.

19. On information and belief, defendants Teva are doing business in New Jersey, have continuous and systematic contacts with New Jersey, have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial district.

20. On information and belief, defendants Cipla are doing business in New Jersey, have continuous and systematic contacts with New Jersey, have engaged in activities together related to the subject matter of this action and are subject to personal jurisdiction in this judicial district.

21. AstraZeneca has sought discovery from Teva relating to the Esomeprazole Magnesium Capsules. Teva has asserted that certain relevant documents and things are not in Teva's possession, custody, or control for purposes of Fed. R. Civ. P. 34 but rather are maintained only by Cipla. To date, Teva has refused to acknowledge its independent obligation to produce such documents and things to AstraZeneca. Teva has failed to produce these documents and things; Teva has failed to procure access to these documents and things from Cipla; Teva has also failed to provide Cipla contact information so that AstraZeneca may

directly address these discovery issues. Moreover, Cipla (through Teva) has refused to stipulate to production of such documents and things as if it were a party to this action.

22. Teva represented that it did not know whether the esomeprazole magnesium in its Esomeprazole Magnesium Capsules infringes.

FIRST CLAIM FOR RELIEF: '504 PATENT

23. AstraZeneca AB, Hässle, AstraZeneca LP, KBI and KBI-E (collectively, "Plaintiffs") reallege paragraphs 1-22, above, as if set forth specifically here.

24. The '504 patent (copy attached as Exhibit "A"), entitled "Compositions," was issued on February 3, 1998 to Astra Aktiebolag upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The patent was subsequently assigned to AstraZeneca AB. The '504 patent claims, inter alia, pharmaceutical formulations comprising alkaline salts of esomeprazole (including esomeprazole magnesium) and methods of using esomeprazole magnesium.

25. Plaintiff AstraZeneca AB has been and is still the owner of the '504 patent. The '504 patent will expire on February 3, 2015 and pediatric exclusivity relating to the '504 patent expires on August 3, 2015.

26. Teva's Notice of Certification notified Plaintiffs that it had submitted an Abbreviated New Drug Application ("ANDA") to the FDA under 21 U.S.C. § 355(j), seeking the FDA's approval to manufacture, use, offer to sell and sell Teva's Esomeprazole Magnesium Capsules as a generic version of the NEXIUM® product.

27. In the Notice of Certification, Teva notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '504 patent. This statutory section

requires, inter alia, certification by the ANDA applicant that the subject patent, here the '504 patent, "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

28. On information and belief, at the time Teva's Notice of Certification was served, Teva was aware of the statutory provisions and regulations referred to in paragraph 21, above.

29. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 22 above), does not allege non-infringement of any of the claims of the '504 patent.

30. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 22 above), does not address unenforceability or inequitable conduct of the '504 patent.

31. In the Notice of Certification, Teva did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 22, above, as to the '504 patent.

32. Teva's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

33. Teva has infringed the '504 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in the this patent, prior to the expiration of the '504 patent.

34. On information and belief, Teva's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Teva's active behest and with its intent, knowledge and encouragement. On information and belief, Teva will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '504 patent.

35. On information and belief, Teva's Esomeprazole Magnesium Capsules are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the claimed esomeprazole magnesium and a pharmaceutically acceptable carrier. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '504 patent.

36. Teva's Notice of Certification does not allege and does not address non-infringement of the claims of the '504 patent. By not addressing non-infringement of the

claims of the '504 patent in its Notice of Certification, Teva admits that its Esomeprazole Magnesium Capsules meets all limitations of the claims of the '504 patent.

37. On information and belief, the manufacture, use and sale of Teva's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

38. To further investigate whether IVAX Esomeprazole Magnesium Capsules infringe the '504 patent claims, in a letter dated February 6, 2006, AstraZeneca requested access to certain documents, information and samples, as well as access to IVAX's ANDA No. 78-003 and the DMFs.

39. AstraZeneca requested the information and samples to "assess infringement of the patents identified in IVAX's notice letter and also AstraZeneca and Merck process patents."

40. AstraZeneca informed IVAX that ANDA No. 78-003 and a sample of the bulk material used to make IVAX's ANDA product were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, IVAX refused to provide AstraZeneca access to any documents other than IVAX's ANDA No. 78-003 and the bulk sample, including refusing to provide access to any of the requested samples.

41. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, information to confirm that IVAX's Esomeprazole Magnesium Capsules infringe the '504 patent claims.

42. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '504 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '504 patent.

43. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and

submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium Capsule for commercial sale in violation of the '504 patent. On information and belief, the information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '504 patent.

44. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '504 patent.

45. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '504 patent by the acts stated above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

SECOND CLAIM FOR RELIEF: '192 PATENT

46. Plaintiffs reallege paragraphs 1-22 and 26, above, as if set forth specifically here.

47. The '192 patent, (copy attached as Exhibit "B"), entitled "Method For The Treatment Of Gastric Acid-Related Diseases And Production Of Medication Using (-)Enantiomer Of Omeprazole," was issued on March 2, 1999 to Astra Aktiebolag, upon

assignment from the inventors Per Lindberg and Lars Weidolf. The patent was subsequently assigned to AstraZeneca AB. The '192 patent claims, inter alia, methods for treatment of gastric acid related diseases by administering a therapeutically effective amount of esomeprazole and pharmaceutically acceptable salts thereof and methods for producing a medicament for such treatment.

48. Plaintiff AstraZeneca AB has been and still is the owner of the '192 patent. The '192 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '192 patent expires on November 27, 2014.

49. In the Notice of Certification, Teva notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '192 patent. This statutory section requires, inter alia, certification by the ANDA applicant that the subject patent, here the '192 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

50. On information and belief, at the time Teva's Notice of Certification was served, Teva was aware of the statutory provisions and regulations referred to in paragraph 40, above.

51. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 40 above), does not allege non-infringement of any of the claims of the '192 patent.

52. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 40 above), does not address unenforceability or inequitable conduct of the '192 patent.

53. In the Notice of Certification, Teva did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 40, above, as to the '192 patent.

54. Teva's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

55. Teva has infringed the '192 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug the use of which is claimed in this patent, prior to the expiration of the '192 patent.

56. On information and belief, Teva's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related diseases by inhibiting gastric acid secretion. On information and belief, such administration will decrease interindividual variation in plasma levels (AUC) during such treatment. On information and belief, such treatment will increase average plasma

levels(AUC) per dosage unit. On information and belief, such treatment will effect a pronounced increase in gastrin levels in slow metabolizers during such treatment. On information and belief, such treatment will effect decreased CYP1A induction in slow metabolizers during such treatment. On information and belief, such treatment will elicit an improved antisecretory effect during such treatment. On information and belief, such treatment will elicit an improved clinical effect comprising accelerated rate of healing and accelerated rate of symptom relief during such treatment. On information and belief the amount to be administered will be between about 20 mg and about 40 mg total daily dose during such treatment. On information and belief, this administration will occur at Teva's active behest and with its intent, knowledge and encouragement. On information and belief, Teva will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '192 patent.

57. On information and belief, Teva's Esomeprazole Magnesium Capsules are especially made or especially adapted to inhibit gastric acid secretion and for use in the treatment of gastrointestinal inflammatory disease via the administration of a therapeutically effective amount of a pharmaceutical formulation containing the magnesium salt of esomeprazole. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '192 patent.

58. Teva's Notice of Certification does not allege and does not address non-infringement of the claims of the '192 patent. By not addressing non-infringement of the claims of the '192 patent in its Notice of Certification, Teva admits that its manufacture and sale of Esomeprazole Magnesium Capsules meets all limitations in those claims.

59. On information and belief, the manufacture, use and sale of Teva's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

60. To further investigate whether IVAX Esomeprazole Magnesium Capsules infringe the '192 patent claims, in a letter dated February 6, 2006, AstraZeneca requested access to certain documents, information and samples, as well as access to IVAX's ANDA No. 78-003 and the DMFs.

61. AstraZeneca requested the information and samples to "assess infringement of the patents identified in IVAX's notice letter and also AstraZeneca and Merck process patents."

62. AstraZeneca informed IVAX that ANDA No. 78-003 and a sample of the bulk material used to make IVAX's ANDA product were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, IVAX refused to provide AstraZeneca access to any documents other than IVAX's ANDA No. 78-003 and the bulk sample, including refusing to provide access to any of the requested samples.

63. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, information to confirm that IVAX's Esomeprazole Magnesium Capsules infringe the '192 patent claims.

64. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '192 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '192 patent.

65. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium Capsule for commercial sale in violation of the '192 patent. On information and belief, the

information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '192 patent.

66. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '192 patent.

67. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '192 patent by the acts stated above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

THIRD CLAIM FOR RELIEF: '872 PATENT

68. Plaintiffs reallege paragraphs 1-22 and 26, above, as if set forth specifically here.

69. The '872 patent, (copy attached as Exhibit "C"), entitled "Compounds," was issued on April 5, 2005 to AstraZeneca AB, upon assignment from the inventors Per Lennart Lindberg and Sverker Von Unge. The '872 patent claims, inter alia, esomeprazole magnesium salts.

70. Plaintiff AstraZeneca AB has been and still is the owner of the '872 patent. The '872 patent will expire on May 27, 2014 and pediatric exclusivity relating to the '872 patent expires on November 27, 2014.

71. In the Notice of Certification, Teva notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '872 patent. This statutory section requires, inter alia, certification by the ANDA applicant that the subject patent, here the '872 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

72. On information and belief, at the time Teva's Notice of Certification was served, Teva was aware of the statutory provisions and regulations referred to in paragraph 58, above.

73. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding non-infringement (see paragraph 58 above), does not allege non-infringement of any of the claims of the '872 patent.

74. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 58 above), does not address unenforceability or inequitable conduct of the '872 patent.

75. In the Notice of Certification, Teva did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 58, above, as to the '872 patent.

76. Teva's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

77. Teva has infringed the '872 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, prior to the expiration of the '872 patent.

78. On information and belief, Teva's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients at Teva's active behest and with its intent, knowledge and encouragement. On information and belief, Teva will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '872 patent.

79. On information and belief, Teva's Esomeprazole Magnesium Capsules are especially made or especially adapted for treatment of humans. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '872 patent.

80. Teva's Notice of Certification does not allege and does not address non-infringement of the claims of the '872 patent. By not addressing non-infringement of the

claims of the '872 patent in its Notice of Certification, Teva admits that its Esomeprazole Magnesium Capsules meets all limitations in the claims of the '872 patent.

81. On information and belief, the manufacture, use and sale of Teva's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

82. To further investigate whether IVAX Esomeprazole Magnesium Capsules infringe the '872 patent claims, in a letter dated February 6, 2006, AstraZeneca requested access to certain documents, information and samples, as well as access to IVAX's ANDA No. 78-003 and the DMFs.

83. AstraZeneca requested the information and samples to "assess infringement of the patents identified in IVAX's notice letter and also AstraZeneca and Merck process patents."

84. AstraZeneca informed IVAX that ANDA No. 78-003 and a sample of the bulk material used to make IVAX's ANDA product were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, IVAX refused to provide AstraZeneca access to any documents other than IVAX's ANDA No. 78-003 and the bulk sample, including refusing to provide access to any of the requested samples.

85. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, information to confirm that IVAX's Esomeprazole Magnesium Capsules infringe the '872 patent claims.

86. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '872 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '872 patent.

87. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and

submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium Capsule for commercial sale in violation of the '872 patent. On information and belief, the information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '872 patent.

88. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '872 patent.

89. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '872 patent by the acts stated above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

FOURTH CLAIM FOR RELIEF: '085 PATENT

90. Plaintiffs reallege paragraphs 1-22 and 26, above, as if set forth specifically here.

91. The '085 patent, (copy attached as Exhibit "E"), entitled "Form of S-Omeprazole," was issued on April 9, 2002 to AstraZeneca AB, upon assignment from the inventors Hanna Cotton, Anders Kronström, Anders Mattson and Eva Möller. The '085 patent

claims, inter alia, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts.

92. Plaintiff AstraZeneca AB has been and still is the owner of the '085 patent. The '085 patent will expire on May 25, 2018 and pediatric exclusivity relating to the '085 patent expires on November 25, 2018.

93. In the Notice of Certification, Teva notified Plaintiffs that, as part of its ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '085 patent. This statutory section requires, inter alia, certification by the ANDA applicant that the subject patent, here the '085 patent, "is invalid or will not be infringed by the manufacture, use, offer to sale or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)) specify, inter alia, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds of supporting the allegation."

94. On information and belief, at the time Teva's Notice of Certification was served, Teva was aware of the statutory provisions and regulations referred to in paragraph 93, above.

95. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding invalidity (see paragraph 93 above), does not allege invalidity of any claims of the '085 patent.

96. Teva's Notice of Certification, which is required by statute and regulation to provide a full and detailed explanation regarding unenforceability (see paragraph 93 above), does not address unenforceability or inequitable conduct of the '085 patent.

97. In the Notice of Certification, Teva did not provide the full and detailed statement required by, and therefore fails to comply with, the statutory and regulatory provisions set forth in paragraph 93, above, as to the '085 patent.

98. Teva's Notice of Certification fails to comply with the law, as specified in 21 U.S.C. § 355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

99. Teva has infringed the '085 patent under 35 U.S.C. § 271(e)(2) by filing its ANDA seeking approval from the FDA to engage in the commercial manufacture, use or sale of a drug claimed in this patent, or the use of which is claimed in this patent, prior to the expiration of the '085 patent.

100. On information and belief, Teva's Esomeprazole Magnesium Capsules, if approved, will be administered to human patients in a therapeutically effective amount to treat gastric acid related conditions. On information and belief, this administration will occur at Teva's active behest and with its intent, knowledge and encouragement. On information and belief, Teva will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

101. On information and belief, Teva's Esomeprazole Magnesium Capsules are especially made or especially adapted to treat gastric acid related diseases via the

administration of a therapeutically effective amount of a pharmaceutical formulation containing esomeprazole magnesium. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules are so made or so adapted. On information and belief, Teva is aware that its Esomeprazole Magnesium Capsules, if approved, will be used in contravention of Plaintiffs' rights under the '085 patent.

102. On information and belief, the manufacture, use and sale of Teva's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

103. To further investigate whether IVAX Esomeprazole Magnesium Capsules infringe the '085 patent claims, in a letter dated February 6, 2006, AstraZeneca requested access to certain documents, information and samples, as well as access to IVAX's ANDA No. 78-003 and the DMFs.

104. AstraZeneca requested the information and samples to "assess infringement of the patents identified in IVAX's notice letter and also AstraZeneca and Merck process patents."

105. AstraZeneca informed IVAX that ANDA No. 78-003 and a sample of the bulk material used to make IVAX's ANDA product were not sufficient to evaluate the allegations in the Notice of Certification. Despite this, IVAX refused to provide AstraZeneca access to any documents other than IVAX's ANDA No. 78-003 and the bulk sample, including refusing to provide access to any of the requested samples.

106. Plaintiffs bring this suit, in part, to employ the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, information to confirm that IVAX's Esomeprazole Magnesium Capsules infringe the '085 patent claims.

107. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '085 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '085 patent.

108. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium Capsule for commercial sale in violation of the '085 patent. On information and belief, the information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '085 patent.

109. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '085 patent.

110. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '085 patent by the acts stated above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

FIFTH CLAIM FOR RELIEF: '789 PATENT

111. Plaintiffs reallege paragraphs 1-22 and 26, above, as if set forth specifically here.

112. United States Patent No. 5,948,789 (the "'789 patent," copy attached as Exhibit "F"), entitled "Process For Synthesis Of Substituted Sulphoxides," was issued on September 7, 1999 to Astra Aktiebolag, upon assignment from the inventors Magnus Erik Larsson, Urban Jan Stenhede, Henrik Sörensen, Sverker Per Oskar von Unge and Hanna Kristina Cotton. The patent was subsequently assigned to AstraZeneca AB. The '789 patent claims, inter alia, processes for the synthesis of sulfoxide compounds.

113. Plaintiff AstraZeneca AB has been and still is the owner of the '789 patent. The '789 patent will expire on July 3, 2015.

114. Teva submitted to FDA an Abbreviated New Drug Application, No. 77-830, seeking FDA's approval to manufacture, use and sell Teva's proposed Esomeprazole Magnesium Capsules as a generic version of the NEXIUM® Delayed-Release Capsules.

115. On information and belief, the process Cipla uses to manufacture the active ingredient in its Esomeprazole Magnesium Capsules will infringe the claims of the '789 patent.

116. On information and belief, Cipla participated in, contributed to, aided, abetted, engaged in activities directed towards and/or induced infringement of the '789 patent. Therefore, Cipla is jointly and severally liable for any infringement of the '789 patent.

117. On information and belief, Cipla has and will continue to provide material information and physical product to Teva in connection with the preparation and submission of ANDA No. 78-003, which seeks approval to offer the Esomeprazole Magnesium

Capsule for commercial sale in violation of the '789 patent. On information and belief, the information and product supplied by Cipla was relied upon and used by Teva in the submission of ANDA No. 78-003. By so doing, Cipla has and will knowingly and intentionally participate in, contribute to, aid, abet, engage in acts directed towards and/or induce the infringement of the '789 patent.

118. On information and belief, Cipla has and will, without authority, manufacture and import into the United States and/or use, offer to sell or sell within the United States the Esomeprazole Magnesium Capsules, or a material part thereof, which Teva then intends to offer for sale under ANDA No. 78-003, if approved, in violation of the '789 patent.

119. There has been and is now an actual justiciable controversy between Teva and Cipla on the one hand and Plaintiffs on the other hand as to whether Teva and Cipla have infringed, will infringe, or have contributed to, induced, aided and/or abetted infringement of or will contribute to, induce, aid and/or abet infringement of the '789 patent by the acts stated above. This is so because Teva and Cipla have and will continue to, without altering course, engage in and make meaningful preparation to engage, in the infringing acts stated above.

120. Upon information and belief, there is a substantial likelihood that the Esomeprazole Magnesium Capsules were made by the patented process. To the extent that AstraZeneca has been unable to determine the process actually used in the production of the product despite making a reasonable effort to do so, Teva and Cipla bear the burden of establishing that the product was not made by the patented process.

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Teva's ANDA No. 78-003 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) for the drug product "Esomeprazole magnesium" must be later than May 3, 2020, the expiration date of the last patent in suit, including pediatric exclusivity relating to the patent, that is infringed;

(b) A judgment declaring that the '504, '192, '872, ~~'810,~~ '085 and '789 patents remain valid, remain enforceable and have been infringed or will be infringed by defendants Teva and/or Cipla if the Esomeprazole Magnesium Capsules are imported into, made, used, offered for sale or sold in the United States prior to the expiration of said patents;

(c) A judgment declaring that Teva has not complied with the requirements of 35 U.S.C. § 271(e)(2), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), 21 U.S.C. § 355(j)(2)(B)(iv), 21 C.F.R. § 314.94 and 21 U.S.C. § 314.95;

(d) A permanent injunction against any infringement by Teva and/or Cipla of '504, '192, '872, '085 and '789 patents;

(e) A judgment that Teva's and/or Cipla's infringement is willful;

(f) A judgment that Teva's and/or Cipla's conduct is exceptional;

(g) Attorneys' fees in this action under 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such other relief as this Court may deem proper.

Dated: December 18, 2008

By: S/Andrew T. Berry

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of December 2008, I caused the foregoing Amended Complaint and supporting papers to be served upon the following counsel via ECF and electronic mail:

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